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Strategies used in improving and assessing the level of reporting of implementation fidelity in randomised controlled trials of palliative care complex interventions: A systematic review

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Abstract

Background: Implementation fidelity is critical in evaluating effectiveness of interventions.

Aim: Identifying and summarising strategies to improve and assess the level of reporting of implementation fidelity in randomised controlled trials of palliative care complex interventions.

Design: Systematic review.

Data sources: Published and completed randomised controlled trials from 2000 to current evaluating effectiveness of specialised palliative care services on patient-centred outcomes in adult patients were examined. MEDLINE was searched from 2008 to 29 September 2015 and supplemented by randomised controlled trials identified in a 2008 systematic review.

Results: Altogether, 20 randomised controlled trials involving 8426 patients were reviewed using 40 subcomponents of five elements of implementation fidelity (resulting in $20 \times 40 = 800$ items). Over 88 strategies were identified, classified under the following elements: 'treatment design', 'training providers', 'delivery of treatment', 'receipt of treatment' and 'enactment of treatment skills'. No single overarching strategy was discovered. Strategies under 'treatment design' aimed to ensure equivalent treatment dose between and within intervention and control groups, and delivery of necessary ingredients. Ongoing 'training (of) providers' included supervision and ensuring skill acquisition. Use of treatment manuals and implementation checklists aimed to aid 'delivery of treatment'. Research teams aimed to improve 'receipt of treatment' by transmitting clear information and verifying understanding, while improving 'enactment of treatment skills' by reviewing and reinforcing prior content. Only 26% of the items received sufficient reporting; 34% were either not used or reported on.

Conclusion: Implementation fidelity in palliative care is under-recognised. A table to collate these strategies to improve implementation fidelity in palliative care research and clinical practice is proposed.

Keywords

Health plan implementation, palliative care, palliative medicine

What is already known about the topic?

- Palliative care is a complex intervention.
- The effectiveness of an intervention can only be determined if there is implementation fidelity (meaning the extent an intervention is implemented as intended).
- Current understanding of implementation fidelity and strategies to improve this have been largely derived from behaviour change interventions, but there has been no analysis of this for palliative care.

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What this paper adds?

- Implementation fidelity in palliative care is under-recognised.
- Strategies used to improve implementation fidelity in randomised controlled trials of palliative care can be categorised under the following elements: 'treatment design', 'training providers', 'delivery of treatment', 'receipt of treatment' and 'enactment of treatment skills'.
- Over 88 strategies have been identified to improve implementation fidelity.

Implications for practice, theory or policy

- A table, modified from the data extraction form used in this review, representing the elements of fidelity, their subcomponents, and showcasing the strategies identified, has been produced.
- The strategies identified could be used, not just in research but in clinical practice, to guide all phases of the development and evaluation of palliative care interventions.
- Substantial administrative burden in the application of the identified strategies suggests that further investigation is required to identify which strategies are more effective in improving, as well as assessing, the level of reporting of implementation fidelity in palliative care interventions.

Introduction

The two conditions for experimental interventions to be adopted as standard care are as follows: they are effective and were implemented with a minimum implementation fidelity standard. Implementation fidelity is important because without it, conclusive statements about the effectiveness of an intervention cannot be made.^{1–8} However, implementation fidelity is challenging in palliative care. Current understanding of implementation fidelity is largely focused on interventions aimed at changing health behaviours,^{1,2,4,5,9} that is, behavioural change interventions, which often only makes up one component of palliative care. Therefore, behavioural change implementation fidelity strategies and findings may not be easily transferable to palliative care, a complex intervention. Palliative care, with a heterogeneous patient population both in terms of primary diagnosis and setting for service delivery,⁶ requires individualised care¹⁰ and becomes ineffective if any of its vital interacting components are left out.^{5,11} Therefore, understanding how to maintain and improve implementation fidelity in palliative care is especially important in order to avoid errors of poor implementation of complex interventions. In this systematic review, we aimed to identify and summarise strategies used in recently published randomised controlled trials (RCTs) of palliative care complex interventions to improve implementation fidelity.

Methods***Theoretical framework and definitions of implementation fidelity***

There is no consistent definition for implementation fidelity. For the purpose of this review, implementation fidelity is defined as 'the extent an intervention is implemented as intended'^{1,12} and interpreted to mean the same

as 'intervention fidelity'⁹ and 'treatment fidelity'.² In order to be inclusive, implementation 'fidelity' has also been interpreted to mean the same as 'integrity'.² Without a universally agreed definition for implementation fidelity, some authors have taken an alternative approach to defining implementation fidelity by elucidating its essential elements. The current understanding of implementation fidelity by its elements is summarised, as in Figure 1, building on existing conceptual frameworks.^{2–4,9,12,13}

As represented in Figure 1, implementation fidelity is thought to have six core elements (in dark blue) each with different components (in light blue). These are 'context', 'design', 'providers', 'delivery', 'receipt' and 'enactment'. Each corresponds to the various stages of an intervention and is examined sequentially below.

The first element is the 'context', or in other words, the 'surrounding social systems, such as structures and cultures of organizations and groups, inter-organizational linkages, and historical as well as concurrent events'¹² of the intervention. While relevant to recognise, 'context' is usually an uncontrollable variable so not many strategies are expected to result therefrom.

The second element is the 'design' which refers to the study's ability to adequately test its hypotheses underlining its theory and clinical processes.² As seen in Figure 1, 'design' has five components.

The first component is the 'theory'² underlining the intervention. The second component is a comprehensive 'protocol' or manual⁹ for implementation of the intervention to ensure ease of replication and evaluation of the intervention, such as detailed guidelines, troubleshooting assistance and setting of standards. The third component is determination of the 'dose' and its ideal and minimally acceptable standards. 'Dose' refers to the frequency and duration of the intervention, and also the content of the

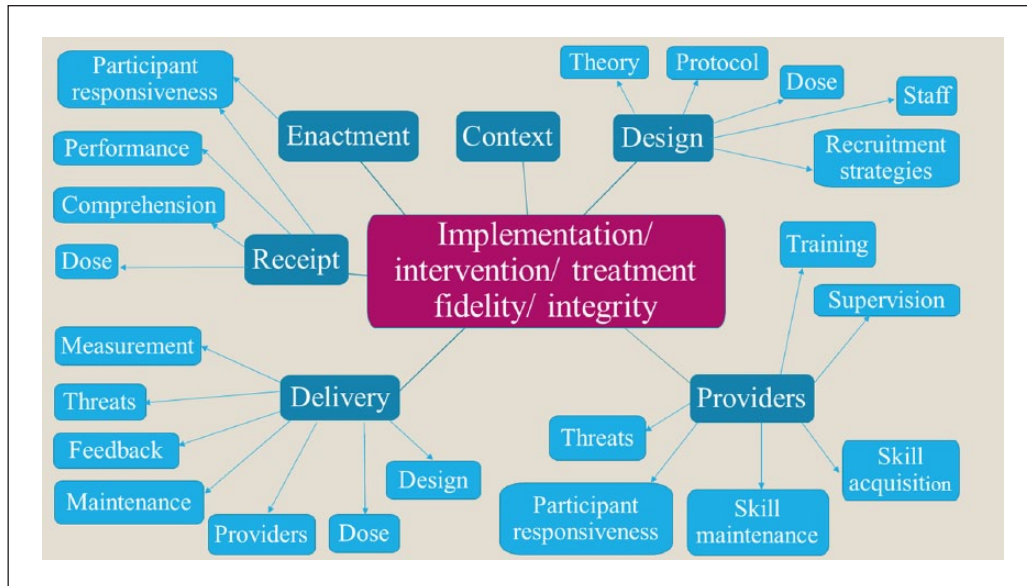


Figure 1. Modified conceptual framework of implementation fidelity.

Adapted from existing conceptual frameworks by Bellg et al.,² Carroll et al.,³ Hasson,¹² Gearing et al.,⁹ Borrelli⁴ and Masterson-Algar et al.¹³

‘dose’ (inclusion of right active ingredients(s) necessary for desired outcomes to be achieved).³ To preserve flexibility, guidance on adaptation can set parameters for dose variations.⁹ The fourth component is ‘staff’ (intervention providers) standards.⁹ The fifth and last component of ‘design’ is ‘recruitment strategies’: procedures used to attract potential intervention participants,¹² as this impacts the extent to which those eligible for the intervention participate in it.³

The third element is the ‘providers’ who should be adequately trained to deliver the intervention, and subjected to assessment and ongoing evaluation.² This influences the quality of delivery, defined as the ‘extent to which the provider approaches a theoretical ideal’.³ This element consists of six components: standardised ‘training’ and ‘supervision’,^{3,9} measures to ensure ‘skill acquisition’ and ‘maintenance’,^{3,4} and ‘participant responsiveness’ (the extent the providers are engaged in an intervention³), as well as countering ‘threats’ to fidelity.

The fourth element is ‘delivery’, which directly impacts quality of delivery.³ This entails monitoring that the intervention is delivered as intended:^{2,3} following the ‘design’ (second element), delivering the intended ‘dose’, adherence to ‘providers’ (third element) standards,² ‘maintenance’ of delivery standards over time and ‘feedback’ on collected fidelity data at each stage of the intervention resulting in corrective adjustments, to address further ‘threats’.^{3,9} Finally, valid and reliable ‘measurement’ of exposures and outcomes⁹ are essential to maintaining delivery.

The fifth element is ‘receipt’ of the intervention. This assesses whether the participant receiving the intervention (assessed by quantity of ‘dose’ received in terms of

frequency, duration and content), ‘comprehends’^{2,9} the intervention, and is able to demonstrate the knowledge or ‘perform’ the intervention skills taught.² ‘Participant responsiveness’, measuring participants’ engagement in the intervention, applies to this and to the next and final element – ‘enactment’.³

The sixth element ‘enactment’ refers to the intervention participant demonstrating knowledge or performing intervention skills in relevant real-life settings.²

Design

We followed standard systematic review methods;¹⁴ the protocol was registered on PROSPERO and can be accessed at http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015027950.

Inclusion and exclusion criteria

Recently published (from 2000 to current) and completed RCTs which had evaluated the effectiveness of specialised palliative care (SPC) complex intervention services on patient-centred outcomes in adult palliative care patients were included. We took the view that these recently published palliative care RCTs would be the most useful source of information on implementation fidelity and an efficient means for a systematic review, given the likelihood that more comprehensive reporting will be found in RCTs which are high-quality evidence,¹⁵ and reporting of recent RCTs was seen to be of higher quality. Pilot and feasibility trials, and trials where only the protocol had been published, were excluded. Studies published in languages other than English were also excluded.

We defined an SPC service as a professional service that provides or coordinates comprehensive care. This was also the definition used in Zimmermann et al.'s¹⁶ systematic review. Only multifaceted or multicomponent complex interventions were included. Drug or procedural trials, and trials evaluating singular variables, for example, communication, were excluded, in order to reflect the complexities of an SPC service. There were no exclusions based on the comparator interventions used as the aim of the review was to identify strategies for improving implementation fidelity, rather than assessing the effectiveness of interventions.

Trials were included if its participants were adult patients requiring palliative care. This meant adult patients with advanced, progressive, symptomatic and life-threatening disease, for whom the focus of care is maximising their quality of life, through expert symptom management, psychological, social and spiritual support. Trials were excluded if the participants targeted were informal caregivers.

Trials were included if they reported on patient-centred outcomes (e.g. symptom control, quality of life, survival or satisfaction). Trials that only reported on one aspect of a patient-centred outcome (e.g. effectiveness of pain medication on pain) were excluded.

Search methods for identification of studies

The search was conducted using MEDLINE from 2008 to 29 September 2015. This was supplemented by published RCTs from 2000 to January 2008 identified through Zimmermann et al.'s¹⁶ systematic review on the effectiveness of SPC services. Key trials (Appendix 1) were identified by experts in the field of palliative care research (I.J.H. and W.G.). Keywords used in the final search were 'palliat\$ or terminal\$ or hospice\$', 'quality of life or well being' and 'randomised controlled trial\$ or randomized controlled trial\$ or RCT or random allocation or randomisation or randomization'. The detailed search strategy can be found in Appendix 2. Searching of other resources, such as grey literature, hand searching reference lists and cited reference searching was not done.

Data collection and analysis

Selection of studies. In considering inclusion/exclusion, a first decision was made by one researcher (K.A.) based on titles and abstracts available. A study was excluded if information clearly indicated that it did not meet the inclusion criteria. When a decision could not be made with certainty, the full paper was inspected. Any doubt in the selection of studies was discussed with a second researcher (I.J.H.) and resolved through consensus. A record of excluded studies and the reasons for exclusion were kept.

Data extraction and management. Data extraction was carried out on the included trials using the 40-item Treatment

Fidelity Assessment and Implementation Plan checklist formulated by National Institutes of Health Behaviour Change Consortium (NIHBC).⁴ This checklist was the most comprehensive and acceptable in pilot-test coding when compared against four other checklists^{5,9,17,18} from the literature review that informed the above-modified conceptual framework (Figure 1). Data extracted from each trial included the following: the author and year of publication, setting (country), number of patients in the trial, brief patient inclusion and exclusion criteria, brief description of the intervention and control intervention, brief research outcomes, the 40 items in the Treatment Fidelity Assessment and Implementation Plan checklist themselves⁴ and also whether or not other strategies outside of those coded in the checklist for use in behaviour change⁴ could be identified. The last item in the checklist⁴ was amended from 'a strategy would be used to *assess* performance ...' (deemed a typo error) to 'a strategy would be used to *improve* performance ...', as published in the original Treatment Fidelity checklist.¹⁸

Where included trials referred readers to previously published studies with likely additional information on implementation fidelity, these referenced studies were retrieved. This was to allow our review to be as inclusive and comprehensive as possible in gathering strategies for implementation fidelity. Strategies were coded on the same checklist such that only one checklist was generated for each trial. A record of the additionally retrieved studies was kept.

Each of the 40 items was rated with 'A' for 'absent but should be present' and 'NA' for 'not applicable'.¹⁸ The 'present' rating¹⁸ was differentiated⁹ into '++' for 'present sufficiently' (especially if there was detailed or extensive coverage/reporting) and '+' for 'present insufficiently' (especially if only briefly mentioned, inferred or one was unsure if it fulfils criteria for 'present sufficiently'). Empty space for free text was also provided such that even if insufficiently present, the strategy used for each of the items could be filled in. Strategies suggested in the 'Discussion' section of the included trials were also described in free text, even if the item was rated as 'A' for absent.

Standard rules for rating were set to maximise reliability in coding, enable differentiation of ratings and optimise the checklist such that it would be applicable to palliative care. Examples provided by Borrelli⁴ were added to guide the coder on what to look out for. Two trials were also pilot-test coded independently by a second researcher (N.H.) and disagreement resolved with further refining of the standard rules. Where consensus was not achieved, the opinion of a third researcher (I.J.H.) was sought and the standard rules further refined to eliminate ambiguity.

Subcomponents of the modified conceptual framework (Figure 1) were also included, with 'training' for the providers interpreted to include supervision, and 'participant responsiveness' interpreted as a means to improve participant comprehension of the intervention. 'Recruitment strategies' was not included as it was thought to be more relevant

to the fidelity of the trial, as opposed to the fidelity of the intervention which is the scope of this review.

K.A. is a physician, while NH holds a doctoral degree; both have a special interest in palliative care. I.J.H. is a consultant in specialist palliative care and also holds a doctoral degree. Inter-coder reliability was not calculated.

Data synthesis

Strategies identified through the data extraction form were coded on the 40-item checklist. Each item was rated ‘++’, ‘+’, ‘A’ or ‘NA’ according to the level of reporting of the strategy and analysed in table form against the five core elements (the first element ‘context’ was not considered as it is usually an uncontrollable parameter):

- ‘treatment design’, that is, whether the study is able to sufficiently test its hypotheses in relation to its underlying theory and clinical processes;²
- ‘training providers’, that is, whether the providers are satisfactorily trained to deliver the intervention and are subjected to assessment and ongoing evaluation;²
- ‘delivery of treatment’, that is, whether the intervention is delivered as intended;^{2,3}
- ‘receipt of treatment’, that is, whether the intervention participant has received and ‘comprehends’^{2,9} the intervention, and is able to demonstrate the knowledge or ‘perform’ the intervention-related skills taught;²
- ‘enactment of treatment skills’, that is, whether the intervention participant is able to demonstrate knowledge or perform intervention-related skills in relevant real-life settings.²

Results

A study flow diagram as recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement¹⁴ is illustrated in Figure 2.

Three papers were excluded upon full inspection. One of these was a quasi-experimental study¹⁹ and two were duplicate publications of results from the ENABLE II trial.^{20,21} The ENABLE II trial was excluded as the intervention was a nurse-led psychoeducation intervention; however, the papers reporting the trial were included as they contain information relevant to implementation fidelity in ENABLE III.²² Another five published RCTs from 2000 to January 2008 identified through Zimmermann et al.’s¹⁶ systematic review were excluded upon full inspection. Further details of the excluded studies can be found in Appendix 3.

Of the key trials used to ensure sensitivity of the search strategy, one could not be recovered in the final search strategy; it was included in the data analysis.^{23–26} Nine papers^{20,21,27–33} which had been referenced in the included

trials were later added to the review as they were likely to contain additional information on strategies used for implementation fidelity.

Description of studies

A total of 46 papers reporting on 20 RCTs of SPC complex intervention services involving 8426 patients were included. In total, 10 trials were conducted exclusively with cancer patients,^{20–22,27,32–51} one exclusively on multiple sclerosis,^{23–26} one exclusively on chronic heart failure,^{52,53} whereas the remaining eight trials were not confined to a single diagnostic group.^{28–31,54–65} All were carried out in developed countries with the majority being in the United States (nine of them)^{20–22,28,30,31,33,39–45,54–57,60–65} and in the United Kingdom (five).^{23–27,29,37,38,58,59}

As the focus of this review was to extract implementation fidelity strategies rather than to evaluate the effectiveness of the interventions used, only brief notes on the study participants, sample size, setting (country), intervention and outcome measured have been tabulated. This table of characteristics of included studies is in Appendix 4.

Strategies for improving implementation fidelity in RCTs of palliative care complex interventions

Under treatment design, an important subcomponent is to ensure the dose is equivalent between and within the intervention and control groups, with similar access and attention to both groups³⁸ and within each group. The latter could be via specifying the number of contacts^{29,58} with a proviso that this could be increased when necessary,^{38,46} or limiting the number of contacts (referring on if more is needed);^{23–26} specifying a range of minutes to be spent;^{48–50} using a ‘structured-visit format’;⁵⁵ or promoting protocol adherence, such as early site visits, review of medical records⁶⁰ and conference calls.^{55,60} Other key strategies identified include (1) specification of provider credentials needed,⁴⁷ (2) specification and incorporation of active ingredients, demonstrating treatment differentiation,^{27,28,34–50,52–54,56,59} (3) use of expert/protocol review groups to determine implementation protocol fidelity to underlying theoretical model and (4) identification of potential confounders.

Under training providers, key strategies include provision of pre-implementation or ongoing training, such as observing experts, working with relevant clinicians, clarifying of job scope,^{27,37} regular supervision sessions,^{20–22,27,33–37} regular didactic sessions by experts,^{28,34–36,56} grand rounds, workshops and video presentations.^{30,31,61–65} Other strategies include role-play practice sessions with feedback to assess provider skill acquisition,^{20–22,33} record and review of intervention sessions to assess provider skill maintenance,^{20–22,33} assessment of providers’ suitability for particular interventions⁵⁴ and appropriate training for trainees from different disciplines.^{30,31,61–65}

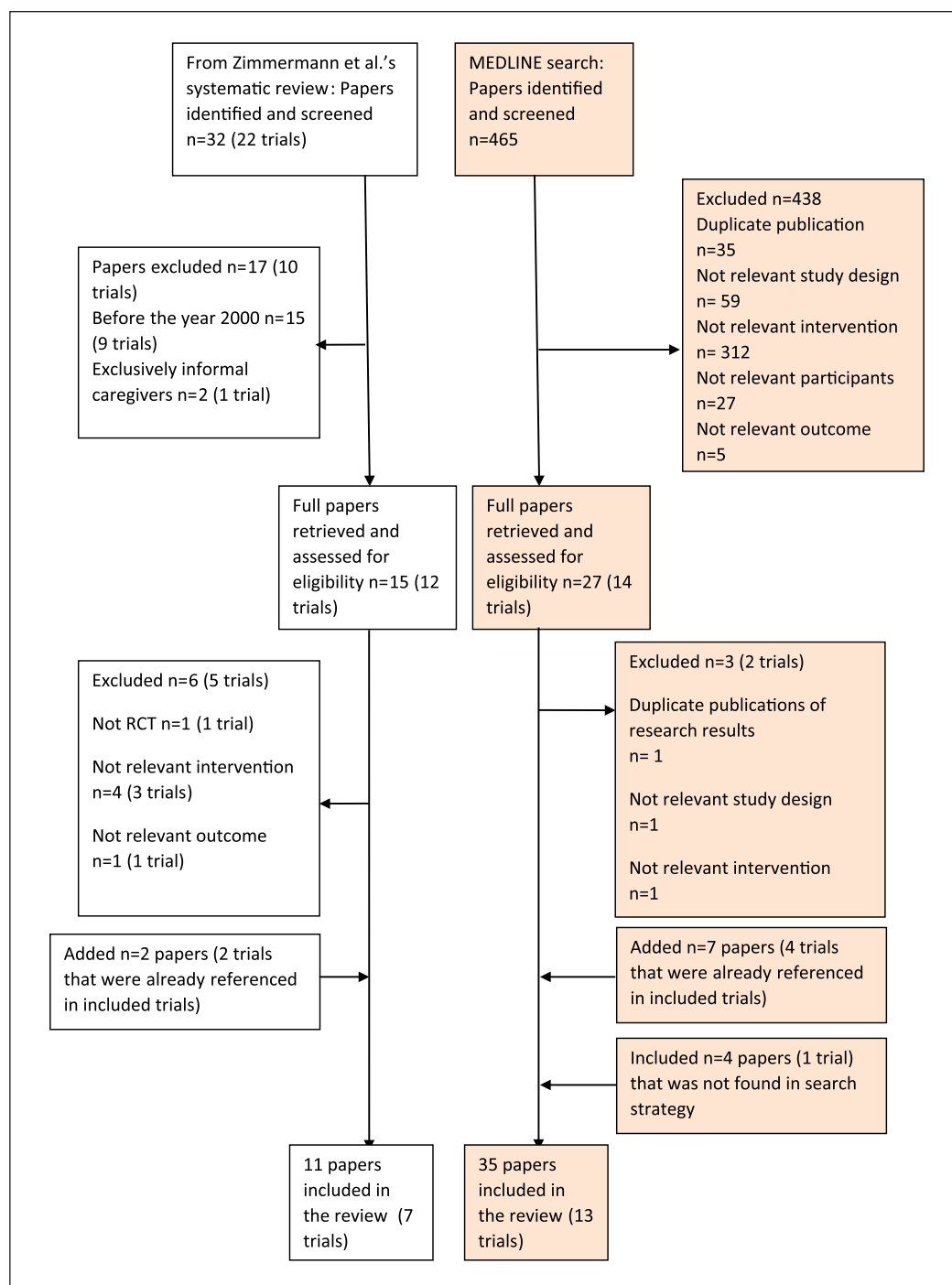


Figure 2. PRISMA flowchart.

For treatment delivery, key strategies are the usage of a treatment manual,^{34–36} usage of an implementation checklist,^{39–44} site visits/surveys to ensure adherence to intervention plan,^{54,60} interviewing patients or caregivers on their experience,^{23–26,29,32,45,51–53,58} checking whether medications given were appropriate,^{32,51} limiting specific intervention to intervention group patients and preventing exposure by control group,⁵⁹ and using a cluster randomised trial

design,^{30–32,34–36,51,61–65} preferably with only one unit of randomisation per cluster and restricting the intervention to trial sites.^{32,51}

In relation to ‘delivery of treatment’, a summary table on the level of reporting of implementation fidelity is presented in Table 1, and the remaining summary tables for the remaining core elements (excluding ‘context’) are presented in Appendix 5. As can be seen from Table 1, only

Table 1. Level of reporting of implementation fidelity strategies in included studies: delivery of treatment.

Trial	Method to ensure that the dose of the intervention is delivered as specified	Method to ensure that the content of the intervention is delivered as specified	Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information	Assessment of non-specific treatment effects	Use of treatment manual	There is a plan for the assessment of whether or not the active ingredients were delivered	There is a plan for the assessment of whether or not proscribed components were delivered	There is a plan for how will contamination between conditions be prevented	There is an a priori specification of treatment fidelity
Hughes et al. ⁵⁴	+	+	++	+	++	++	+	++	A
Jordhoy and colleagues ^{34–36}	+	+	A	A	++	A	A	++	A
Hanks et al. ⁵⁹	+	+	++	+	++	+	+	++	A
Moore et al. ^{27,37}	+	+	++	A	++	+	A	++	A
Engelhardt et al. ⁵⁵	++	++	++	A	++	++	A	A	A
Aiken et al. ^{28,56}	+	+	++	A	++	+	A	A	A
Brumley et al. ⁵⁷	+	+	A	A	++	A	A	A	A
Higginson and colleagues ^{23–26}	+	+	++	++	++	+	+	++	A
Gade et al. ⁶⁰	+	+	++	A	++	++	A	A	A
Molassiotis et al. ³⁸	+	+	++	A	++	+	A	++	A
Temel et al. ^{39–44}	++	++	++	A	++	+	A	++	A
Wallen et al. ⁴⁵	+	+	++	++	++	+	+	A	A
De Raaf et al. ⁴⁶	+	+	A	A	++	A	A	++	A
Brannstrom and Boman ^{52,53}	+	+	A	++	++	A	+	A	A
Uijtdehaag et al. ⁴⁷	+	+	A	A	++	A	A	++	A
Bausewein et al. ²⁹ and Higginson et al. ⁵⁸	+	+	++	++	++	+	+	A	A
Zimmermann et al. ^{48–50}	+	+	++	A	++	+	A	++	A
Bakitas et al. ^{20–22} and Maloney et al. ³³	+	+	++	+	++	++	+	A	A
Curtis and colleagues ^{30,31,61–65}	+	+	++	+	++	++	+	++	A
Costantini et al. ^{32,51}	+	+	++	++	++	+	++	++	A

'A' for 'absent but should be present'; 'NA' for 'not applicable'; '++' for 'present sufficiently', especially if there was detailed or extensive coverage; '+' for 'present insufficiently', especially if it was briefly mentioned, inferred or one was unsure if it fulfils criteria for 'present sufficiently'.

about one-third (62 items) of the strategies were sufficiently reported (rated ‘+++’), while another third (60 items) were either not used or reported (rated ‘A’); none of the trials mentioned having set a standard for implementation fidelity that the trial would have to meet.

For receipt of treatment, key strategies are having a health literacy component,⁵⁵ having patients recall intervention suggestions, considering ‘participant responsiveness’ and recruitment of willing patients,^{34–36} assisting with understanding of medical terminology,⁵⁵ providing access to information adjusted for health literacy,^{28,55,56} answering questions,^{28,38,56} verifying understanding,^{28,39–44,56} summarising information^{29,58,60} and providing an information pack.^{29,58} Rehearsal of emergency situations and practising self-monitoring and reporting of patients’ results^{28,56} would aid in assessment of patients’ receipt. Consideration of cross-cultural communication in the educational component,^{30,31,61–65} amending feedback method for outcome data by removing ranking numbers, de-identifying comments, emphasising positive findings and positively presenting low score as opportunities for improvement^{30,31,61–65} were used to improve receipt.

Finally, key strategies for assessment of enactment include checking self-monitoring diaries, the status of earlier referrals and compliance with medical regime,^{28,29,56,58} while reinforcing prior content^{20–22,28,29,33,56,58} improves enactment.

These strategies are summarised in Table 2 (in black text). No other strategies for improving implementation fidelity outside of the elements used in behaviour change and coded outside the checklist⁴ were identified. We also did not find examples of strategies that tried to alter the context of the implementation environment to facilitate implementation of the intervention.

Out of the 800 items rated (40 items for each of the 20 trials), 270 items were rated ‘A’ (34%), 159 ‘+’ (20%), 209 ‘+++’ (26%) and 162 ‘NA’ (20%). When the individual trial was considered, less than 50% of the 40 items were rated ‘+++’. The detailed extracted data are available from the corresponding author. Appendix 6, sorted into the five core elements (excluding ‘context’), presents a summary of strategies used and suggested, including the strategies which were insufficiently described, for improving implementation fidelity.

Discussion

This is the first systematic review of strategies used to improve implementation fidelity in RCTs of palliative care complex interventions. By reviewing and rating 20 recently published SPC service RCTs involving 8426 patients, we have shown that implementation fidelity in palliative care is under-recognised, with up to a third of assessed items rated ‘absent’ and another 20% insufficiently reported on. Moreover, it does not seem that the studies had intentionally reported on implementation fidelity. Nevertheless,

over 88 strategies have been identified, sub-classified under the following elements: ‘treatment design’, ‘training providers’, ‘delivery of treatment’, ‘receipt of treatment’ and ‘enactment of treatment skills’. The list of strategies for each item should be viewed as a whole rather than individually as certain items rated absent may still have been accomplished partially in other items. Strategies were not mutually exclusive and can support several goals. The use of these strategies, albeit mostly in cancer patients in developed countries, suggests that the strategies are applicable to other palliative care RCTs.

Strategies in palliative care covered all subcomponents except for two: (1) having a plan to ensure that the measures reflect the hypothesised theoretical constructs/mechanisms of action and (2) an a priori specification of treatment fidelity. Although a potential source of administrative burden, theoretical underpinnings have been recognised as crucial for the success in complex interventions.⁶⁶ Similarly, high fidelity requires at least 80% adherence, with 50% considered low.⁴ Although palliative care is a complex intervention, of which behaviour change may only constitute one component, no additional strategies outside of those coded in the checklist for use in behaviour change⁴ could be identified. This suggests that strategies used in behaviour change and other fields, not yet identified as used in palliative care RCTs, may be used to improve implementation fidelity in palliative care RCTs and palliative care interventions in general, and that palliative care researchers could work more closely with behaviour change researchers.

As such, Table 2, modified from the data extraction form used in this review, incorporates examples of strategies used in behaviour change interventions⁴ in green text. The strategies identified in this review have also been added on to the data extraction form in black text, as examples of strategies used in palliative care trials, for use in assessing the level of reporting of implementation fidelity. These examples provided would assist future coders on what to look for. The standard rules used in data extraction are in red text.

The strategies identified in this review could be used, not just in research but in clinical practice, to guide all phases of the development and evaluation of palliative care interventions,⁶⁶ to ensure that they are implemented more efficiently and produce more trustworthy results. However, there is also substantial administrative burden in the practical application of these strategies. Administrative burden is brought on by evaluating the ‘delivery of treatment’ and also in ‘training providers’ by having to assess skill acquisition in intervention providers trained to deliver the intervention, and to continually evaluate that they have maintained their skills.

An additional column for strategies identified from papers other than the main paper dealing with the trial has also been added to the data extraction form used in this

Table 2. Recommended data extraction form along with the standard rules and examples of strategies used.

Trial identifier by author and year of publication of results	Use this column to code information that was not found in the original article
Setting (country)	
Number of patients	
Brief patient inclusion and exclusion criteria	
Brief description of intervention vs control	
Brief research outcomes	
Treatment design	
1. Provide information about treatment dose planned for in the intervention condition	
(a) Length of contact (minutes) (no need to elaborate) (NA if the dose is on an as-needed basis)	
(b) Number of contacts (no need to elaborate) (NA if the dose is on an as-needed basis)	
(c) Content of treatment (no need to elaborate)	
(d) Duration of contact over time (no need to elaborate)	
2. Provide information about treatment dose planned for in the comparison condition	
(a) Length of contact (minutes) (no need to elaborate) (NA if the dose is on an as-needed basis)	
(b) Number of contacts (no need to elaborate) (NA if the dose is on an as-needed basis)	
(c) Content of treatment (no need to elaborate) (+ if only mentions 'usual care'/absence of the intervention implying usual care, without further elaboration of what usual care constitutes)	
(d) Duration of contact over time (no need to elaborate) (NA if the dose is on an as-needed basis)	
(e) Method to ensure that dose is equivalent between conditions (NA if the dose is on an as-needed basis)	
E.g. Provide similar access and attention to both groups (withholding only the intervention)	
(f) Method to ensure that dose is equivalent for participants within conditions (NA if the dose is on an as-needed basis; ++ if adequately describes the dose and can, where applicable, be equivalent for each subject)	
E.g. Specify the number of contacts; and add a proviso that this could be increased when necessary; limit the number of contacts (refer on if more is needed); specify a range of minutes to be spent; use a 'structured-visit format'; promote protocol adherence, such as early site visits, review of medical records and conference calls	
3. Specification of provider credentials that are needed (+ if only the professional discipline is known; ++ if level of experience is known)	
E.g. Specify professional discipline and level of experience, e.g., specialist nurse with more than 10 years of experience in oncology nursing care	
4. Theoretical model upon which the intervention is based is clearly articulated	
(a) The active ingredients are specified and incorporated into the intervention (+ if elaborates on what the essential components of the intervention might be; ++ if explains factors distinguishing it from the comparison condition, i.e., differentiation)	
E.g. Specify and incorporate essential components of the intervention, and how the intervention differs from the control group	
(b) Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines (+ if self-derives protocol from reviews or known theoretical models; ++ if uses a panel of experts, protocol review group or advisory committee)	
E.g. Provide reasons for selecting the intervention evaluated, e.g., reviews or theoretical models, and use experts or protocol review group. Examples used were: cooperative study group, project advisory committee, project advisory group and trial study group	
(c) Plan to ensure that the measures reflect the hypothesised theoretical constructs/mechanisms of action (++ if the outcome measures selected and used by the study adequately assesses the hypothesised theory behind the intervention)	

(Continued)

Table 2. (Continued)

<p>5. Potential confounders that limit the ability to make conclusions at the end of the trial are identified (A if confounders identified was that there was no method to ensure the dose equivalence within or between treatment groups; + if baseline demographics measured, or baseline outcome measures measured; ++ if other confounders identified, or if strategies to get around confounders used)</p> <p>E.g. Measure baseline demographics and baseline outcome measures, where applicable</p> <p>Additional confounders identified were as follows: evaluating a recently started existing service such that the providers involved have not had sufficient experience with the intervention routines; relying on existing community services which may be limited in palliative care competence and resources; the extra attention the intervention group would get; the complexity of the intervention and heterogeneity of the patient group; having a relative who was an intervention provider or working with one; the exclusion of a patient group that was most likely to benefit</p> <p>Sources of contamination were as follows: a focus on palliative care by providers for the control group regardless of whether it was brought on by publicity on palliative care, education of control group providers as part of the intervention or provider participation in both arms; access by the control group to palliative and supportive interventions</p> <p>Strategies: recruit patients early in their disease trajectories, yet frequently symptomatic, with a higher likelihood of participating and benefiting from the intervention; obtain administrative and clinical backing; address common obstacles in palliative care, such as inability or unwillingness to engage in decision-making, early in the intervention</p>	
<p>6. Plan to address possible setbacks in implementation (i.e. backup systems or providers) (++) even if only mentioned having sufficient manpower)</p> <p>E.g. Have adequate manpower (but this was not foolproof as large numbers increase unreliability, which warrant minimising with training); a backup system, e.g., repeated video-screening giving all targeted participants an opportunity to view the video</p>	
<p>7. If more than one intervention is described, all described equally well (NA if two-armed RCT)</p>	
Training providers	
<p>1. Description of how providers will be trained (manual of training procedures) (interpreted to include supervision and maintenance protocols) (NA if all the providers designed intervention/uses existing service; + if only mentioned that there was training provided, ++ if details on training methods for either pre-implementation or ongoing training of providers are available)</p> <p>E.g. Pre-implementation training: observing experts; working with relevant clinicians; clarifying of job scope; making links with providers of similar services; independent reading; role-playing with feedback</p> <p>Methods used for ongoing training: regular telephone calls or meetings to discuss implementation issues; regular supervision sessions; regular advice; joint visits if necessary; regular didactic sessions by experts, grand rounds, workshops, or video presentations; system supports such as palliative care order forms that facilitate learning through personal experience; spontaneous teaching moments and discussions of clinical cases; bedside training; coaching, telephone and direct guidance; identification and training of local champions; feedback of quality data; clinical audits for difficult cases; reviewing implementation to develop more appropriate training strategies; using suitable tools for consolidation of the changes</p>	
<p>2. Standardisation of provider training (especially if multiple waves of training are needed for multiple groups of providers) (NA if only one trainee/if all the providers designed intervention/used existing service; + if inferred 'standardisation' or only standardised a component of the intervention)</p> <p>E.g. Use the same trainers over time, use certified trainers, train all providers together, use standardised training materials, use video or audio tapes of expert delivery, develop a manual of training procedures and videotape trainings in case of provider attrition and need for future trainings</p>	
<p>3. Assessment of provider skill acquisition (interpreted to be pre-implementation of intervention; + if 'assessment' inferred, ++ if details provided on how the assessment was done)</p> <p>E.g. Use role-plays with standardised patients followed by feedback to provider, score provider adherence to both intervention content and process using validated performance criteria, have a written exam pre and post training, develop criteria for initial certification</p> <p>E.g. Practice sessions in the form of role-playing with feedback</p>	

Table 2. (Continued)

<p>4. Assessment and monitoring of provider skill maintenance over time (+ if 'supervision/feedback' is inferred; ++ if details provided on assessing or monitoring)</p> <p>E.g. Booster sessions, patient exit interviews, periodic re- certification, audio or video record all encounters and code for treatment adherence, provide timely feedback, monitor patient drop-out rates of each provider</p> <p>E.g. Review intervention patients' medical records; review audio-recorded intervention sessions; assess inter-rater reliability of assessments by providers against that by research associates; collection and feedback of outcome data and meetings to discuss barriers to achieving the outcome</p>	
<p>5. Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori (A if only provider credentials mentioned; NA if all the providers designed intervention/used existing service; + if inferred that providers were chosen)</p> <p>E.g. Choose providers of appropriate disciplines with appropriate skills; or who have 'institutional identity and credibility' being familiar with institutional policies and having ongoing relationships with clinicians whom they would need to work together with in the intervention</p>	
<p>6. At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g. ensure that providers find the intervention acceptable, credible, and potentially efficacious) (NA if all the providers designed intervention/used existing service; + if inferred that the providers found the intervention potentially efficacious prior to the start of the trial)</p> <p>E.g. Hire providers with similar credentials and experience. Ensure 'buy in' to treatment, theory and randomisation. Consider matching providers to key characteristics of the population</p> <p>E.g. Enhance buy-in from providers: Foster provider self-efficacy and perception of organisational support. Explain the study design and rationale, the principles of research and why it is important to prevent contamination and omission or addition of components not specified by the intervention</p> <p>E.g. Conduct intervention at centres which already have a similar service and which the provider is interested in evaluating its new yet similar service</p>	
<p>7. There is a training plan that takes into account trainees' different education and experience and learning styles (NA if all the providers designed intervention/used existing service)</p> <p>E.g. Design training for diverse learning styles, train providers to deal with different types of participants, consider more intensive training and follow-up for less experienced providers</p> <p>E.g. Train different disciplines differently; evaluate its implementation mid-way to develop an appropriate strategy for the subsequent implementation stages</p>	
Delivery of treatment	
<p>1. Method to ensure that the dose of the intervention is delivered as specified (interpreted 'as specified' as 'adequate levels'; dose here excludes content) (+ if used a treatment protocol, or if details of treatment are available; ++ if there is both assessment and feedback of dosage, or if provider records number of contact minutes or uses a checklist)</p> <p>E.g. Use an implementation checklist; use a template (according to protocol guidance) in the electronic medical record to document the care provided</p>	
<p>2. Method to ensure that the content of the intervention is delivered as specified (interpreted 'as specified' as 'adequate levels') (+ if used a treatment protocol, or if details of treatment are available; ++ if there is both assessment and feedback of dosage, or if provider records care given on a standardised questionnaire, has to report protocol deviations, or uses a checklist)</p> <p>E.g. Use an implementation checklist; use a template (according to protocol guidance) in the electronic medical record to document how much of the visit was spent on each element of the intervention</p>	
<p>3. Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information (+ if mentioned; ++ if details provided)</p> <p>E.g. Site visits or surveys; regular telephone conferences; regular meetings; interview patients or their formal caregivers; participant observation by research staff at site meetings; monitoring administrative databases; examine treatment implementation checklists for a randomly selected subset of patients; review audio-recorded intervention sessions for adherence; take attendance at intervention sessions; keep patient records</p>	

(Continued)

Table 2. (Continued)

<p>4. Assessment of non-specific treatment effects (e.g. empathy, communication style) (+ if inferred assessment; ++ if purpose of interview was focussed on assessing non-specific treatment effects, or experience)</p> <p>E.g. Assess non-specific effects through multiple methods and on an ongoing basis (patient exit interview, audiotape and code sessions, monitor participant complaints, provide feedback to provider)</p> <p>E.g. Ask patients and/or carers about their experiences of the intervention</p>	
<p>5. Use of treatment manual (++) if details were provided, or if the word 'manual' or its synonyms, e.g., protocol were used)</p> <p>E.g. Use scripted curriculum or treatment manual</p>	
<p>6. There is a plan for the assessment of whether or not the active ingredients were delivered (+ if inferred that there is a plan; ++ if data was collected for such purpose and details on how it was collected is available)</p> <p>E.g. Apart from reporting on mechanisms available for assessment of provider adherence, trials were required to report that data were collected for such purpose and provide details on how the data were collected</p> <p>This included the following: site visits or surveys; regular telephone conferences; regular meetings; interviewing patients; participant observation by research staff at site meetings; monitor administrative databases; examine treatment implementation checklists for a randomly selected subset of patients; review audio-recorded intervention sessions for adherence; take attendance at intervention sessions; review patient records</p>	
<p>7. There is a plan for the assessment of whether or not proscribed components were delivered (e.g. components that are unnecessary or unhelpful) (+ if inferred that there is a plan or enquired about experiences; ++ if purpose of interview was focussed on assessing negative non-specific treatment effects or experiences)</p> <p>E.g. Judged if medications given had been inappropriate</p>	
<p>8. There is a plan for how will contamination between conditions be prevented</p> <p>E.g. Limit access to the specific intervention evaluated to intervention group patients; limit control group exposure by using a limited form of the intervention and discouraging crossover unless absolutely necessary; use a cluster randomised trial design preferably with only one unit of randomisation per cluster and restricting the intervention to trial sites; being the only provider for specialist palliative care; keeping control patients' details from the provider to avoid inadvertent contact; disqualifying patients who may have relatives working as or with intervention providers</p> <p>Similarly, a strategy for preventing contamination in the intervention group included limiting their access to control group interventions, e.g., by making the intervention providers responsible for the entire care of the patients</p>	
<p>9. There is an a priori specification of treatment fidelity (e.g. providers adhere to delivering >80% of components)</p> <p>E.g. Establish minimum competency levels, below which providers are given remedial training (e.g. adherence to ≤80% of the components)</p>	
Receipt of treatment	
<p>1. There is an assessment of the degree to which participants understood the intervention (+ if inferred assessment or training)</p> <p>E.g. Have a health literacy component; have patients recall intervention suggestions, such as who to contact after hours, resources available, and self-management of illness; assess patients' illness and prognostic understanding; assess patients' understanding of explanations given</p>	
<p>2. There are specification of strategies that will be used to improve participant comprehension of the intervention (interpreted engaging patient (participant responsiveness) as a means to improve comprehension of the intervention; A if only mentioned 'training'; + if strategy inferred; ++ even if one component of the intervention, as long as it was explicitly to improve comprehension)</p> <p>E.g. Consider 'participant responsiveness' and recruit only willing patients; assist understanding of medical terminology; provide access to information adjusted for health literacy; answer questions; verify understanding; summarise information; provide an information pack; use lectures, video and pamphlets; reinforce prior content; provide access to personally relevant resources</p>	

(Continued)

Table 2. (Continued)

<p>3. The participants' ability to perform the intervention skills will be assessed during the intervention period (interpreted the intervention period as while the palliative care direct contact is taking place. In interventions without educational components, this would be, e.g., filling up the diary in front of the provider vs enactment, e.g., filling up the diary in between contact with the provider. Facilitating discussions or goal setting is thought of as an intervention rather than a performance of skills during the intervention period)) (+ if inferred assessment/training)</p> <p>E.g. 'Rehearse' emergency situations and 'practice' self-monitoring and reporting of results with patients</p>	
<p>4. A strategy will be used to improve subject performance of intervention skills during the intervention period (interpreted the intervention period as while the palliative care direct contact is taking place) (A if only mentioned 'training'; + if strategy inferred)</p> <p>E.g. Rehearse emergency situations; practicing self-monitoring and reporting of results</p>	
<p>5. Multicultural factors considered in the development and delivery of the intervention (e.g. provided in native language; protocol is consistent with the values of the target group) (A if native language is the language of the majority)</p> <p>E.g. Encourage local adaptation of order forms and pamphlets; amend feedback method for outcome data by removing ranking numbers, de-identifying comments, emphasising positive findings and positively presenting low score as opportunities for improvement</p>	
Enactment of treatment skills	
<p>1. Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied (e.g. filling up the diary in between contact with the provider or self-management in times of crises. Facilitating discussions, decisions or goal-setting is thought of as an intervention rather than a performance of skills) (+ if inferred assessment)</p> <p>E.g. Check self-monitoring diaries; check status of earlier referrals; check compliance with medication regime; check use of interventions, e.g., hand held fan for breathlessness</p>	
<p>2. A strategy will be used to improve performance of the intervention skills in settings in which the intervention might be applied (A if only mentioned 'training'; + if inferred; ++ even if one component of the intervention, as long as it was explicitly to improve enactment)</p> <p>E.g. Reinforce prior content; have written instructions of the intervention written and laminated (in a poem or in a chart)</p>	
Strategies that are not included in any of these boxes	

Coding scheme: 'A' for 'absent but should be present'; 'NA' for 'not applicable'; '++' for 'present sufficiently' especially if there was detailed or extensive coverage; '+' for 'present insufficiently' especially if it was briefly mentioned, inferred, or one was unsure if it fulfils criteria for 'present sufficiently'.

Each grey area is one component.

Colour code: quotes from the National Institutes of Health Behaviour Change Consortium (NIHBCC)⁴ are in blue, standard rules inserted by the author in red, examples provided by Borrelli⁴ in green and examples (strategies rated '++') from the current review provided in black.

review (see Table 2). The proportion of trials in which a strategy had been sufficiently present, or the mean proportion of adherence to strategies for each trial, could then be calculated.¹⁸

With the use of the TIDieR checklist and guide,⁶⁷ which aims to improve the completeness of reporting of interventions by supplementing the CONSORT⁶⁸ and SPIRIT⁶⁹ statements, and which has 2 out of its 12 items dedicated to fidelity, the level of reporting of interventions is likely to improve. The TIDieR checklist and guide⁶⁷ suggest that both the planning and actual delivery of an intervention in terms of fidelity should be described, and that the description should include how intervention fidelity was 'assessed and by whom, the strategies that were used to maintain or improve fidelity', and the extent to which the intervention

was delivered as planned (which also pertains to 'delivery of treatment'). The use of Table 2 could also improve levels of reporting and reduce the proportion of items rated 'A'. Table 2 could be updated if additional strategies are identified. The proportion of 'A' and '+' ratings could also be used to track if the reporting of implementation fidelity has improved over time and provide an estimate of the acceptability and interpretability of the table when reporting and awareness of implementation fidelity are optimised.

Aside from Table 2, to optimise face and content validity, it would be best to consult an international implementation fidelity workgroup in palliative care to ensure that the modified checklist captures the views of all these stakeholders. Consensus on what would constitute a sufficient level of reporting, especially in the differentiation

between ‘+’ and ‘++’, and ‘A’ and ‘NA’, and if each strategy identified ought to be scored individually, and whether certain aspects of implementation fidelity should be more heavily weighted than others, could be sought. The question of how much information on implementation fidelity is needed for an informed decision as to whether or not the intervention was implemented with a minimum implementation fidelity standard, and therefore adequately evaluated the intervention tested, can then be answered.

Limitations

This review is subjected to biases. There was bias in sample selection from searching only MEDLINE for completed RCTs on adult patients that were published in English, although experts in palliative care research were consulted to identify key trials (Appendix 1) to ensure that the final sample of trials retrieved would be as representative as possible. We also did not search trial registers for other papers reporting our included trials, for example, process evaluations. This could be a limitation of the study if papers detailing implementation fidelity were published at a later date. Measurement bias likely prejudices the level of implementation fidelity found in each trial, given the wide variation in level of reporting and limited word count in single publications, although data from multiple reports of the same trials were extracted onto a single checklist. To improve reporting in single publications, authors could be encouraged to publish fidelity information in an online resource and in their appended study protocol.

Conclusion

Implementation fidelity in palliative care is under-recognised. Nevertheless, over 88 strategies have been identified in palliative care RCTs. The use of these strategies and those identified in behavioural change interventions, along with greater awareness on the subcomponents of the elements of implementation fidelity (see Table 2), will be valuable in improving, as well as evaluating, implementation fidelity. Needless to say, more funds are needed in palliative care for education to maintain the minimum fidelity standard, facilitate the implementation of essential components of a complex intervention and to support the development and evaluation of research and clinical services.⁷⁰

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Supplementary materials

Underlying research materials related to the paper are available from the corresponding author.

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